

## PRESS RELEASE

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# Genetic Immunity Presents Clinical Data on DermaVir Patch Immune Therapy at 15th Annual Conference on Retroviruses and Opportunistic Infections

Data Shows Excellent Safety Profile and Long Lasting Immunity



**McLean, Virginia and Budapest, Hungary, February 11, 2008** – Genetic Immunity, a US/Hungarian clinical-stage biopharmaceutical company focusing on the development of its patented immunotherapeutic platform technology, announced clinical safety and immunogenicity data on its DermaVir Patch, a topically administered HIV immune therapy. The presentation, titled, “Single DermaVir Patch Treatment of HIV+ Individuals Induces Long Lasting, High Magnitude and Broad HIV-Specific T Cell Responses,” was given at the 15th Annual Conference on Retroviruses and Opportunistic Infections (CROI) in Boston, February 3-6, 2008.

Presently available antiretroviral drugs interfere with the viral life cycle, but because of their toxicity and resistance profiles are typically prescribed as late as possible in the disease progression. Recent findings with DermaVir Patch treatment suggest that this innovative medicine induces new HIV specific immune responses in HIV infected patients not achievable by antiretroviral drugs. Such an alternative treatment approach has the capability to address the needs of those HIV positive individuals who have not yet begun drug therapy as well as those who are currently on drug therapy.

Genetic Immunity studied nine HIV infected individuals on fully suppressive antiretroviral therapy who were treated a single time with either 0.1, 0.4 or 0.8 mg of multiple HIV antigens encoding plasmid DNA, the active substance in DermaVir Patch. The same antiretroviral drug regimen was continued during the one-year follow-up.

HIV-specific T cell Precursors with High Proliferative Capacity (PHPC) were quantified via an assay performed by Franco Lori, M.D. and his collaborators. The DermaVir Patch treatment resulted in significant induction of PHPC counts in all nine patients in the study. Importantly, these precursor T cell responses were long lasting, 10-100 fold increased PHPC counts over baseline were detected during the one year follow up. An independent study has demonstrated that PHPC count inversely correlates with viral load.

Safety was assessed with standard clinical and laboratory evaluations, and dermatological analysis of skin reaction. DermaVir Patch continued to show a lack of dose limiting toxicities. Through multiple studies, the only side effect seen so far has been limited to transient erythema (redness of the skin).

Julianna Lisziewicz, Ph.D., Co-Founder and CEO of Genetic Immunity, said, “The distinctive safety and immunogenicity data is consistent with our primate studies showing viral load reduction associated with immune responses induced by DermaVir Patch treatment. The Genetic Immunity team is encouraged by this data, which suggests that the DermaVir Patch is on its way to becoming the first immune therapy for HIV-infected individuals.”

Franco Lori, M.D., CEO of Virostatics said, “In an independent experiment, we demonstrated that high PHPC counts significantly correlate with low viral load. The clinical results of the DermaVir Patch suggest a novel immunogenicity profile. We are hopeful that many patients may see benefit from this truly innovative antiviral therapy.”

## About Genetic Immunity®

Genetic Immunity is a US/Hungarian development stage company establishing leadership in next-generation biopharmaceuticals. The Company is leveraging its proprietary platform technology to create new markets for infectious diseases, cancer and allergy through the discovery, development and commercialization of topically administered immune therapies. These indications represent significant unmet medical need and potential for alternative treatment approaches. Genetic Immunity's lead product, the DermaVir Patch for the treatment of HIV/AIDS, was discovered by the Company's founders, and is in Phase II clinical development with the opportunity to be the first immune therapy approved for HIV-infected individuals.

## About DermaVir Patch

The proprietary DermaVir Patch is a topically administered HIV immune therapy, which emerged from the clinical observations of Genetic Immunity's founders. Their examination of the "Berlin Patient" proved that induction of immune control of HIV replication is feasible in an infected patient. The Company has developed the DermaVir Patch to induce the immune system to kill HIV infected cells specifically and to make immune therapy accessible for the majority of HIV infected individuals, including children. The DermaVir Patch, currently in Phase II clinical trials, is comprised of two patented components: NanoComp and DermaPrep. NanoComp is an antigen composition platform that combines a disease-specific plasmid DNA with the Company's formulation technology. The unique DNA for the DermaVir Patch product encodes the majority of HIV antigens, allowing a broad immune response. DermaPrep is a topical administration device by which NanoComp is delivered specifically into the dendritic cells.

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